

In the Specification:

Please amend the specification, page 1, first paragraph, as follows:

This application is a continuation-in-part of Ser. No. 09/860,916~~8~~, filed May 18, 2001 and entitled, "Stress-Induced Connecting Assembly", which is a continuation-in-part of Ser. No. 09/523,719, filed March 11, 2000 and entitled, "Stress-Induced Interposed Connector" (U.S. Patent No. 6,257,59~~5~~3), which is a continuation-in-part of Ser. No. 09/311,938, filed May 14, 1999 and entitled "Stress-Induced Seal", now abandoned. This application is further based on prior Provisional Application Ser. No. 60/262,362, filed January 19, 2001 and entitled Drive Shaft Coupling. The entire disclosures of these afore-mentioned applications are expressly incorporated by reference herein and relied-upon.

... and third paragraph, extending to page 2, line 14, as follows:

It is commonly known that nitinol (formally known as Nickel Titanium Naval Ordinance Laboratory, but other super-elastic nickel-titanium alloys being included in this definition) tubing, wire or rod can be used as a mechanical drive shaft. The use of metallic SUPER-elastic alloys, such as Ni--Ti (nitinol) and other bi- or tri-metal alloys, has been documented in a variety of technical applications, including fasteners, connectors, gaskets, clamps and seals. Many such uses have required temperature in order to activate the material and change its physical state, while others have used mechanical forces that impart stress to cause a SUPER-elastic physical deformation in the material. Of particular concern to the instant inventor is the application of the SUPER-elastic material to connectors. The use of non-corrosive, metallic SUPER-elastic material offers a decided advantage in high performance connecting assemblies, versus more conventional connectors requiring threaded fasteners, springs, clamps or other holding or securing mechanisms. Particularly it can withstand more wear than

alloys used in conventional connectors due to its harder surface characteristics. It can also withstand extreme vibrations and not loosen due its elastic pre-loaded condition without using conventional adhesives to hold the assembled components and/or the connector itself together. Adhesives used with conventional connectors make them very difficult to disassemble, whereas it is generally possible to make a SUPER-elastic connector completely reversible.

U.S. Pat. No. 5, 683,404 to Johnson, entitled "Clamp and Method for its Use", further discusses shape memory materials that are "pseudo-elastic", defining these materials in terms of their ability to exhibit SUPER-elastic/pseudo-elastic recovery characteristics at room temperature. Such materials are said to deform from an austenitic crystal structure to a stress-induced structure postulated to be martensitic in nature, returning thence to the austenitic state when the stress is removed. The alternate crystal structures described give the alloy SUPER-elastic or pseudo-elastic properties. Poisson's Ratio for nitinol is about 0.3, but this ratio significantly increases up to approximately 0.5 or more when the shape memory alloy is stretched beyond its initial elastic limit. It is at this point that stress-induced martensite is said to occur, i.e., the point beyond which the material is permanently deformed and thus incapable of returning to its initial austenitic shape. A special tool is employed by Johnson to impart an external stretching force that deforms the material which force is then released to cause the material to return to its original condition. While the device is stretched, a member is captured by it and securely clamped when the stretching force is released. This device is intended for use in clamping and does not contemplate traditional connecting operations of the kind addressed by the present invention. Another use envisioned by Johnson is in connecting the modular components of a medical device, as described in his U.S. Pat. No. 5,858,020, by subjecting a thimble component made of shape memory material to an external stretching stimulus to elongate and thereby reduce its transverse dimension. Upon release of the stretching force, this component returns towards its original rest dimension, contacting and imparting a force on another component. This is a sequential stretching and relaxation of the SUPER-elastic

material rather than a simultaneous activation and retention operation. Also, special structures are necessary on the thimble to allow the stretching force to be imparted.

In U.S. Pat. No. 5,197,720 to Renz, et al., a work piece is held within a clamping tool by an expansion element made of shape memory material that is activated by mechanical force. In this way, torque is transmitted through the shape memory member. This device is useful for bringing parts together for holding the work piece in order to perform an operation. It does not, however contemplate a use as a connector. U.S. Pat. No. 5,190,546 to Jervis discloses insertion into a broken bone cavity of a split member made of shape memory material using a SUPER-elastic alloy. The split member holds the walls of the bone cavity when radial compressive forces acting on it are released. In order for the radial compressive force to reduce the diameter, the component must be split, allowing the reduction in dimension for insertion. It does not act as an interposed member in a connecting assembly.

Others have sought to utilize the properties of shape memory materials as locking, connector and bearing elements, e. g., U.S. Pat. No. 5,507,826 to Besselink, et al., U.S. Pat. No. 5,779,281 to Kapgan, et al., and U.S. Pat. No. 5,067,827 to Arnold, respectively; however, such approaches have required temperature to be applied during use. U.S. Pat. No. 5,277,435 to Kramer, et al. and U.S. Pat. No. 5,876,434 to Flomenblit, et al, similarly has relied upon temperature to activate the shape memory effect. Such dependence on extrinsic activation by temperature introduces an added process step and may further be disadvantageous in certain other applications.

U.S. Pat. No. 5,842,312 to Krumme, et al., entitled, "Hysteretic Damping Apparati and Methods", employs shape memory tension elements to provide energy dissipation. Such elements can be placed between building structures, etc., which are subject to vibration, serving to absorb the energy created by their relative movement. However, this patent does not contemplate the vibration dampening effect of a SUPER-elastic material in the formation of a connector.

Nitinol is especially useful for transmitting torque while in a bowed or bent shape. These types of drive shafts have proven useful in orthopedic surgical applications where drilling or reaming of curved bones is necessary. One application

is to use a drill or reamer with a nitinol drive shaft to clean out the center of a femoral bone before implanting a prosthesis or femoral nail. These bones typically have a bow with a 90-inch radius and require a flexible reamer for the procedure. Nitinol tubing can be used for this application since it is cannulated and can be passed over a guide wire that is placed down the femur before the reaming process begins. Since the tubing is solid it is very easy to clean after the surgical operation since there are no crevices for blood to get trapped in. Earlier designs utilized spring drive shafts and cleaning was extremely difficult since blood could get trapped between the windings of the spring. The earlier spring designs also had difficulties when run in the reverse direction since springs tend to be strong while being used in one direction, however when run in the opposite direction they tend to unwind. To prevent this unwinding problem several manufacturers have added an additional spring inside of the primary spring, which is wound in the opposite direction. Since one spring is inside of the other this contributes to the difficulties with cleaning and further obviates the need for an alternative shaft design.

On page 3, immediately after line 21, please insert the following:

Accordingly, there is a need to form a connecting assembly using a durable metallic, non-corrosive connector assembly, which are simple to install using relative motion to activate the assembly.

There is a further need to form a secure connection between components that minimizes the micro-motional wear characteristics of the assembly, enhancing its useful life.

There is another need to form a fastened assembly that does not require temperature for its activation.

There is still a need to form an assembly using a fastener that adjusts for differences in thermal coefficients of expansion or contraction of dissimilar materials comprising those components being fastened.

There is still a further need for a connector with elastic properties that allow more forgiving tolerances during manufacturing of the assembly components.

On page 7, in the first paragraph, beginning on line 9, please amend as follows:

Referring to FIGS. 1-3 and particularly FIG. 1, the present invention includes a drive shaft 5 made of a super-elastic alloy, preferably a nickel-titanium commonly known as nitinol. Shafts made from this type of alloy can be formed with a cannulation 7 as shown in FIG. 3 and exhibit the distinctive characteristic of transferring torque while subjected to high bending forces during use. The exemplary use of the present invention is in orthopedic drilling and reaming devices; however, the usage of super-elastic alloys according to the invention has much broader applications encompassing both medical as well as other industrial applications. A device of the present invention is generally shown at 13 in FIGS. 2-3. Tool fitting 20 may be a cutting tool fitting (as shown in FIG. 1) and preferably has a cannulation 22 that is aligned with another cannulation 7 formed in shaft 5 when device 13 is assembled according to the present method. The aligned cannulations 7, 20 allow device 13 to be placed over the top of a guide wire (not shown). Tool fitting 20 also has a radially moveable, i.e., flexible collet portion 25, which is preferably an integral structure although the fitting may be separate from the radially flexible, split portion as discussed below in conjunction with another embodiment (FIGS. 4-6). According to the present method, shaft 5 is slid into collet 25. Preferably there is an interference fit between the outer diameter D1 of shaft 5 and the inner diameter D2 of collet 25. This interference causes collet 25 to bend out in a flower configuration as shaft 5 and fitting 20, are slid together.

On page 7, amend the paragraph beginning on line 27, as follows:

Once tubular shaft 5 has been slid into collet 25, a compression sleeve 10 (FIGS. 1-3) is slid over the flower shaped collet 25 and welded at junction 12. As

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these components 5, 10, 25 are assembled, the collet 25 is forced radially onto the shaft causing a super-elastic activation of the alloy forming the shaft to thereby effect a secure coupling. This super-elastic reaction allows the fingers of collet 25 to contact the tube along the length L1 as shown in FIG. 3. This surface-to-surface contact (shown at 30 in FIG. 3) allows the device 13 to transmit torque. In essence the components are transmitting torque via friction. Thus, whenever the frictional forces are overcome by application of too much torque to the tool fitting 20, the fitting and shaft 5 break free of one another to slip rotationally. This slippage limits the amount of torque that can be applied to the shaft. The contact surface 30 can be adjusted by design to change the length L1, in turn, adjusting the maximum applicable torque limit to ensure that the slippage occurs before the maximum yield strength is reached in shaft 5.

On page 9, please amend the paragraph beginning on line 22 as follows:

An additional sleeve 110 can be added and welded at junction 112 with an optional polymer sleeve 115 pre-assembled inside. The purpose of the polymer sleeve is to transfer bending stress through the tool fitting 120 in a uniform manner to the shaft 105 during use in a bent configuration. This smoother transition ensures premature failure of the fitting. The use of this polymer sleeve 115 may only be necessary when the design of the wall thickness of the tool fitting 120 becomes thin, somewhere on the order of .25 mm to 1mm. Other wise the tool fitting 120 will be able to handle the stress eliminating the necessity for the additional polymer sleeve 115 and sleeve 110.

REMARKS

In order to promote administrative efficiency and better communication, the Examiner is invited to make suggestions at any time during the proceedings, via phone,

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